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10/773,316	02/09/2004	Yasuhiro Matsumura	1021.43503X00	1058

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EXAMINER

HARRIS, ALANA M

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1643

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/773,316	Applicant(s) MATSUMURA ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 0200.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02/09/04; 12/05/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments and Amendments

1. The Examiner of record has changed. Contact information is provided at the close of this Action.

2. Claims 1-10 and 12-21 are pending.

Claims 1-9, drawn to non-elected inventions are withdrawn from consideration.

Claims 10 and 12-14 have been amended.

Claims 16-21 have been added.

Claim 11 has been cancelled.

Claims 10 and 12-21 are examined on the merits.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The rejection of claims 11 and 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the cancellation of claim 11.

Claim Rejections - 35 USC § 102

5. The rejection of claims 10 and 12-15 under 35 U.S.C. §102(e) as being anticipated by Obiso et al. (U.S. Patent Publication 2003/0059839, filed 05/21/2002) is withdrawn in light of the introduction of new matter and claim amendments. Claim 11 has been cancelled. Applicants are put on notice with the deletion of the new matter this rejection may be reinstated.

6. The rejection of claims 10 and 13-15 under 35 U.S.C. §102(b) as being anticipated by Roche et al. (U.S. Patent 5,891,651, issued 04/06/1999) is withdrawn in light of Applicants' amendments to the claims and the addition of new matter. Applicants are put on notice with the deletion of the new matter this rejection may be reinstated.

7. The rejection of claims 10 and 13-15 under 35 U.S.C. §102(e) as being anticipated by Nair (U.S. Patent 6,534,280, filed 03/30/2000) is withdrawn in light of Applicants' amendments to the claims and the addition of new matter. Applicants are put on notice with the deletion of the new matter this rejection may be reinstated.

Claim Rejections - 35 USC § 103

8. The rejection of claims 10 and 12-15 under 35 U.S.C. §103(a) as being unpatentable over Roche et al. (U.S. Patent 5,891,651, filed 03/29/1996) in view of

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Trudil et al. (US Patent 6,176,836, issued 01/23/2001) is withdrawn in light of the cancellation of the amendments to the claims and the addition of new matter. Claim 11 has been cancelled. Applicants are put on notice with the deletion of the new matter this rejection may be reinstated.

9. The rejection of claims 10 and 12-15 under 35 U.S.C. §103(a) as being anticipated by Nair (U.S. Patent 6,534,280; filed 03/30/2000) in view of Trudil et al. (US Patent 6,176,836, issued 01/23/2001) is in light of the cancellation of the amendments to the claims and the addition of new matter. Claim 11 has been cancelled. Applicants are put on notice with the deletion of the new matter this rejection may be reinstated.

New and Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 10 and 12-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claim 10, line 6 to include the recitation, "a solid carrier having a surface having an affinity for cancer cells;". Applicants assert support for this recitation is provided on page 11, lines 9-15 of the specification. While Applicants seem to have support for an antibody with an affinity for cancer cells, this is not the same as that listed in the claim. The surface is distinct from the antibodies, therefore Applicants' amendment is not supported by the specification.

Applicants have also included in claim 10, lines 9 and 10, "...a dispensing portion for dispensing the filtered solution directly into the container." Applicants direct the Examiner's attention to Figure 4 and page 13, lines 14-20, Remarks, page 6, first paragraph. The specification cites "...filtered liquid is dispensed and agitated...", however there is no support for a cell recovery apparatus having a dispensing portion. And the Figure does not disclose a cell recovery apparatus with a section deemed a dispensing section.

And lastly, new claim 21 seems not be supported by the specification although Applicants suggest it is so by Fig 4; page 13, lines 14-24; and page 19, lines 10-21, see page 6 of the Remarks, 2nd paragraph. The Examiner has also reviewed these sections of the specification and does not agree with Applicants. There seems to be no support for the negative limitation or negative proviso, a cell recovery apparatus that does not include a centrifuge.

And while support does not need to be *ipsis verbis* [i.e., "in the same words"] to be sufficient, the claimed invention must be in possession of the inventor at the time of filing. Applicants' specification is remiss of support evidencing contemplation and

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possession of what the Examiner has cited herein and of record in Applicants' amended and new claims. Applicants must delete the new matter or adequately show where support is for the amended and new claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 10 and 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication number 2003/0059839 (filed May 21, 2002), and further in view of U.S. Patent number 6,176,836 B1 (issued January 23, 2001) and WO 97/09600 (filed April 25, 2002/ IDS reference number 5, submitted December 5, 2006).

The publication teaches a cell recovery apparatus containing one or more containers with a solid carrier, such as magnetic beads and a sterile stomacher-type bag, see page 2, paragraph 17, lines 1-7; page 3, section 0044, lines 1-4; page 7, section 00138; page 9, section 0146, lines 1, 2, 9, and 10; page 9, paragraph 157, lines 1-7. Given the stomacher bag of the publication and that, which is claimed, is the same the filter is provided in the bag. The container provides an agitating means to agitate the sample and filtering the sample with one or more filters, see page 6, sections 103 and 105. Absent evidence to the contrary, the publication teaches that the filter is connected to the bag, the container is connected to the filter and the recovery magnet is

provide near the container. The publication teaches the samples may or may not be heat inactivated, thereby providing no temperature control means, see page 12, section 0174, lines 9-11; page 5, paragraphs 67 and 83, lines 1 and 2. The publication does not teach that a centrifuge is used in the cell recovery apparatus, see the claims.

The publication does not teach a dispensing portion for dispensing the filtered solution directly into the container and a plurality of filters are between pore size 400 and 1000 μ m and the solid carrier is BerEP4 antibody-binding magnetic bead. However, the publication and the patent suggest implementing various filters and patent '836 teaches dispersing devices for depositing and holding the sample. And the WO document teaches beads coated with antibody Ber-EP4, which are capable of binding epithelial cells such as colon epithelial cells, see publication, page 1, section 0007, page 2, section 0017; patent's abstract; WO document, page 11, lines 15-30. Applicants' claim 10 seems to define a dispensing portion as a segment of the apparatus, which allows dispersal of the filtered solution into the container. The dispersing device of patent '836 meets this limitation. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention to use filters with differing sizes and add a dispensing portion to the apparatus of patent '836, as well as implement the beads of the WO document. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success to implement the teachings of all documents in the claimed method because the patent teaches a biological sample collection kit using a filter and the subsequent sampling of filtered sample into a collection or container for assays, i.e. dispensing, see column 2, lines 41-

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45. The patent teaches filters serve the purpose of keeping out large, extraneous material and an apparatus having all the materials in one package limits the risk of contamination of the sample and erroneous results, see column 1, lines 18-21; and column 2, lines 36-40. This results in a cell recovery apparatus for isolating cells from a stool sample that is more efficient, see patent '836 column 1, lines 21-24.

And one of ordinary skill in the art would have been motivated to utilize the BerEP4 antibody-binding magnetic beads of the WO document with a reasonable expectation of success because the said document teaches the successful isolation of cells from a faecal stool and further purifying cells using these immunomagnetic beads, see WO's abstract.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER


Alana M. Harris, Ph.D.

30 April 2007